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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,766	04/29/1999	EUIRO WATANABE	0020-4559P	6045

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/301,766

Applicant(s)

WATANABE ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,16-23,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 7 is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8-10,16-23,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 31 August 2005 has been entered.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments to the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claim 16 is objected to because of the following informalities: At line 1 the phrase "a nucleic acid" should read -- the nucleic acid -- in referring to claim 1 as a matter of form. In addition the claim should state that the nucleic acid is operably linked to a promoter not just joined. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1, 4, 5, 8-10, 16-23 and 28-29 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 March 2005. Applicant's arguments filed 31 August 2005 have been fully considered but they are not persuasive.

Arguments directed to SEQ ID NO: 1 are considered moot in view of Applicants' amendments to the claims.

Applicants argue that SEQ ID NO: is specifically disclosed in the present specification, for instance, refer to the originally filed Sequence Listing (page 8 of the Response). Applicants argue that Wallach relates to a claim to any and all genes encoding a TNF cytotoxic activity, which claims are based on description of only the amino-terminal portion of the TNF protein, no DNA sequences were provided, nor was even any full-length protein sequence provided. Applicants argue that the Wallach panel decided that, on these facts, adequate description of any and all genes encoding a TNF cytotoxic activity was not provided. Applicants argue that on the other hand, in the present application at least two complete sequences of raffinose synthase genes are provided (i.e. SEQ ID NOS: 4 and 6), as are their translated amino acid sequences (SEQ ID NOS: 3 and 5) (pages 8-10 of the Response). These arguments are not found to be persuasive because Applicants have not established the function of the amino acid sequences of SEQ ID NO: 5 or 7.

Applicants argue that SEQ ID NO: 7 of the present invention is an amino acid sequence consisting of 572 amino acids (corresponding to about 70% of the full length amino acid sequence of raffinose synthase), this amino acid sequence has a homology

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of about 98% to the amino acid sequence from amino acid 206 to amino acid 777 of SEQ ID NO: 5. Applicants further argue that the nucleotide sequence of SEQ ID NO: 8, also disclosed, encodes the amino acid sequence of SEQ ID NO: 7, and that the specification also discloses the method for obtaining the full-length nucleotide sequence based upon the approximately 70% sequence (page 10, 2nd paragraph of the Response). These arguments are not found to be persuasive for the reasons given *supra*. Claim 1 states that the polynucleotide encodes a protein with a specific activity, yet it is unclear that the protein described in SEQ ID NO: 7 would have such an activity as claimed.

Applicants argue that they specifically claiming a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 3, that SEQ ID NO: 3 represents a complete amino acid sequence of a raffinose synthase. Applicants further argue that it is unnecessary to disclose the corresponding nucleic acid sequences which could encode SEQ ID NO: 3 (page 11 of the Response). Applicants appear to misconstrue the Examiner's arguments which are directed to the fact that Applicant has failed to establish a function for the amino acid sequence depicted in SEQ ID NO: 3, hence it is unclear if Applicant has described nucleotide sequence encoding a protein having the claimed function.

Applicants argue that claim 1, limitation (i) has been cancelled, limitations (g) and (h) (formerly limitations (j) and (k)) relate to nucleotide sequences which are obtained via PCR amplification, this should not be a barrier to patentability since Applicants have specifically recited the source in limitation (g) as beet and in limitation (k) as mustard or

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rapeseed, further, the specific primers and hybridization conditions are recited for each limitation (page 12, 3rd paragraph of the Response). This argument is not found to be fully persuasive. Beet can encompass a variety of plants, for instance, *Beta altissima* Steud., *Beta brasiliensis* hort. ex Voss, *Beta chilensis* hort., *Beta cicla* (L.) L., *Beta vulgaris* var. *altissima* Döll, *Beta vulgaris* subsp. *cicla* (L.) W. D. J. Koch, *Beta vulgaris* var. *cicla* L., *Beta vulgaris* cv. *conditiva* Alef., *Beta vulgaris* var. *crassa* Alef., *Beta vulgaris* subsp. *flavescens* Lam., *Beta vulgaris* var. *flavescens* (Lam.) DC., *Beta vulgaris* f. *rhodopleura* (Alef.) Helm, *Beta vulgaris* cv. *saccharifera* Alef. Mustard or rapeseed can encompass a large genus of plants *Alliaria petiolata* (M. Bieb.) Cavara & Grande (garlic mustard), *Brassica carinata* A. Braun (Abyssinian mustard, Ethiopian mustard, mustard collard), *Brassica juncea* (L.) Czern. (India mustard, Indian mustard, Oriental mustard), *Brassica juncea* var. *crispifolia* L. H. Bailey (curled mustard, cut-leaf mustard, dissected-leaf mustard, southern curled mustard), *Brassica juncea* var. *foliosa* L. H. Bailey (leaf mustard), *Brassica juncea* var. *japonica* (Thunb.) L. H. Bailey (cut-leaf mustard, dissected-leaf mustard), *Brassica juncea* var. *juncea* (brown mustard, Indian mustard), *Brassica juncea* var. *longidens* L. H. Bailey (hakka mustard), *Brassica juncea* var. *multiceps* N. Tsen & S. N. Lee (chicken mustard, multishoot mustard, nine-head mustard), *Brassica juncea* var. *napiformis* (Pailleux & Bois) Kitam. (large-root mustard, root mustard, tuberous-root mustard, turnip-root mustard), *Brassica juncea* var. *rugosa* (Roxb.) N. Tsen & S. N. Lee (cabbage-leaf mustard, head mustard, Swatow mustard), *Brassica juncea* var. *strumata* N. Tsen & S. N. Lee (chopped mustard, horned mustard, large-petiole mustard), *Brassica juncea* var. *tumida* N. Tsen & S. N. Lee (big-stem

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mustard, swollen-stem mustard), *Brassica nigra* (L.) W. D. J. Koch (black mustard), *Brassica rapa* subsp. *campestris* (L.) A. R. Clapham (field mustard), *Brassica rapa* subsp. *chinensis* (L.) Hanelt (celery mustard, Chinese mustard, mustard cabbage, white celery mustard), *Brassica rapa* subsp. *narinosa* (L. H. Bailey) Hanelt (broad-beak mustard), *Brassica rapa* var. *perviridis* L. H. Bailey (spinach mustard), *Brassica rapa* var. *purpuraria* (L. H. Bailey) Kitam. (purple-stem mustard), *Brassica* spp. (wild mustard), *Brassica tournefortii* Gouan (African mustard), *Bunias orientalis* L. (hill mustard), *Chorispora tenella* (Pall.) DC. (blue mustard, musk mustard, purple mustard), *Cleome gynandra* L. (bastard-mustard), *Conringia orientalis* (L.) Dumort. (hare's-ear mustard), *Descurainia incana* (Bernh. ex Fisch. & C. A. Mey.) Dorn (gray tansy mustard), *Descurainia pinnata* (Walter) Britton (tansy mustard, western tansy mustard), *Descurainia torulosa* Rollins (Wyoming tansy mustard), *Diplotaxis tenuifolia* (L.) DC. (sand mustard), *Erucastrum gallicum* (Willd.) O. E. Schulz (dog mustard), *Erysimum cheiranthoides* L. (wormseed mustard), *Erysimum repandum* L. (treacle mustard), *Eutrema penlandii* Rollins (Penland alpine fen-mustard), *Glaucocarpum suffrutescens* (Rollins) Rollins (shrubby reed-mustard), *Neslia paniculata* (L.) Desv. (ball mustard), *Rapistrum rugosum* (L.) All. (common giant mustard), *Schoenocrambe argillacea* (S. L. Welsh & N. D. Atwood) Rollins (clay reed-mustard), *Schoenocrambe barnebyi* (S. L. Welsh & N. D. Atwood) Rollins (Barneby's reed-mustard), *Sinapis alba* L. (white mustard), *Sinapis alba* subsp. *alba* (white mustard), *Sinapis arvensis* subsp. *arvensis* (wild mustard), *Sisymbrium altissimum* L. (tumble mustard), *Sisymbrium officinale* (L.) Scop. (hedge mustard, tumble mustard), *Thelypodium stenopetalum* S. Watson

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(slender-petal mustard), *Thlaspi arvense* L. (Mithridate mustard), *Turritis glabra* L. (tower mustard), *Warea carteri* Small (Carter's mustard).

6. Claims 1, 4, 5, 8-10, 16-23 and 28-29 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 5, plants transformed therewith and methods of using such isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids encoding raffinose synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 1 March 2005. Applicant's arguments filed 31 August 2005 have been fully considered but they are not persuasive.

Applicants argue that the present claims are fully enabled, based upon the level of skill in the art, those of skill would be able to make and use the presently claimed subject matter without undue burden (page 13 of the Response). This argument is not found to be persuasive for the reasons of record. The art teaches that raffinose synthase enzymes have high overall amino acid sequence homology with seed imbibition proteins and stachyose synthases, hence amino acid sequence similarity cannot be used to assert function (see Peterbauer *et al* 2002, *Planta* 215: 839-846, see page 840, left column and page 841, right column). Peterbauer *et al* 1999 (*The Plant Journal* 20(5): 509-518 teach that they believed that they were the first to isolate a nucleotide sequence encoding a stachyose synthase (see page 510, left column, 2nd

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paragraph). The teachings of Peterbauer *et al* 1999 is after the filing date of the instant application indicating that this critical knowledge was not readily know to those of skill in the art at the time of Applicant's invention. Peterbauer *et al* 1999 teaches that stachyose synthase and raffinose synthase have substantial sequence similarity over their entire amino acid sequence at page 511. Hence, given the general skill of those of skill in the art, the nature of raffinose synthase enzymes relatedness of other enzymes and the limited guidance by Applicants it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use raffinose synthase encoding nucleic acids as broadly claimed. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Conclusion

7. Claims 6 and 7 are allowed.
8. Claims 1, 4, 5, 8-10, 16-23 and 28-29 remain rejected.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

**DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER**



David H. Kruse, Ph.D.
23 November 2005

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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